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EXAMINER

KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 11-12-2002

27

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/311,689

Applicant(s)

RAO ET AL.

Examiner

Kathleen M Kerr

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 9-25,28-31,54-59,61,63-67,69-73,76-87 and 96-99 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9,19,21,22,25,28,30,31,54,55,57-59,61,63-67,70,72,76-84,87,96 and 97 is/are allowed.
- 6) ☒ Claim(s) 29,98 and 99 is/are rejected.
- 7) ☒ Claim(s) 10-18,20,23,24,56,69,71,73,85 and 86 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Application Status***

1. In response to the previous Office action, a Final rejection (Paper No. 24 mailed on May 3, 2002), Applicants filed a request for continued examination (RCE) and an amendment and response (Paper No. 26 received on September 3, 2002). Said amendment amended the Abstract and Claims 9, 12, 14, 18, 19, 21, 28-31, 59, 61, 63, 64, 69, 70, 72, 76, 78-84, and 87, cancelled Claims 32, 60, 62, 68, 74, and 75, and added new Claims 98 and 99. Thus, Claims 9-25, 28-31, 54-59, 61, 63-67, 69-73, 76-87, and 96-99 are pending in the instant application and will be examined herein.

### ***Priority***

2. As previously noted, the instant application is granted the benefit of priority of U.S. Application Nos. 08/740,682, filed on November 1, 1996, and 09/297,418, filed on April 30, 1999. It is noted that continuation-in-part benefit of both U.S. applications is claimed and the pending claims may not be afforded priority back to the earliest effective filing date in each case.

### ***Drawings***

3. As previously noted, the drawings have been approved by the Draftsmen and are entered as formal drawings acceptable for publication upon the identification of allowable subject matter.

### ***Compliance with the Sequence Rules***

4. In response to the previous requirement to comply with the sequence rules (Paper No. 24, paragraph 5), Applicants attempted to amend the specification on pages 50-54 with substitute

Art Unit: 1652

sheets. This is not an appropriate procedure for the entry amendments; these amendments to pages 50-54 have not been entered. Applicants must appropriately request the entry of amendments using the procedures noted in M.P.E.P. § 714.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to **fully** comply with the requirements of 37 C.F.R. § 1.821 through 1.825; Applicants' attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990).

- a) On pages 50-54, several oligonucleotides are disclosed without benefit of SEQ ID NOs.
- b) On page 56, several short amino acid sequences are disclosed without benefit of SEQ ID NOs (\*\*the Examiner notes that these sequences are newly cited for compliance).

If the noted sequences are in the sequence listing as filed, Applicants must amend the specification to identify the sequences appropriately by SEQ ID NO. If the noted sequences are not in the sequence listing as filed, Applicants must provide (1) a substitute copy of the sequence listing in both computer readable form (CRF) and paper copy, (2) an amendment directing its entry into the specification, (3) a statement that the content of the paper and CRF copies are the same and, where applicable, include no new matter as required by 37 C.F.R. § 1.821 (e) or 1.821(f) or 1.821(g) or 1.821(b) or 1.825(d), and (4) any amendment to the specification to identify the sequences appropriately by SEQ ID NO.

***Withdrawn - Objections to the Specification***

- 5. Previous objection to the Abstract for not completely describing the disclosed subject matter is withdrawn by virtue of Applicants' amendment to the Abstract.

Art Unit: 1652

6. Previous new matter objection against the disclosure is withdrawn in its entirety.

Applicants have cancelled the new matter or the Examiner has reconsidered the position on the objection by virtue of the all-encompassing disclosure of any polypeptide described in the specification as related to the percent identities cited and/or the modification using disulfide bonds.

***Withdrawn - Claim Objections***

7. Previous objection of Claim 62 under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn by virtue of Applicants' cancellation of said claim.

***Withdrawn - Claim Rejections - 35 U.S.C. § 112***

8. Previous rejection of Claim 12 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "wild-type Cl-2" is withdrawn by virtue of Applicants' amendment.

9. Previous rejection of Claim 14 under 35 U.S.C. § 112, second paragraph, as being indefinite for the transitional phrase that should be ---further comprising--- is withdrawn by virtue of Applicants' amendment.

10. Previous rejection of Claim 18 under 35 U.S.C. § 112, second paragraph, as being indefinite for the word "about" is withdrawn by virtue of Applicants' amendment.

11. Previous rejection of Claims 29, 32, and 62 under 35 U.S.C. § 112, second paragraph, as being indefinite for the terms "conservatively modified" and "conservatively substituted" is

withdrawn, in part (Claims 32 and 62 have been cancelled), by virtue of Applicants' amendment to try and obviate the rejection. A new, similar rejection is set forth below.

12. Previous rejection of Claims 59, 61, 72, 74, 76, 78-84, and 87 and their dependent claims (Claims 60, 62-71, 73, 75, 77, 85, and 86) under 35 U.S.C. § 112, first paragraph, new matter, is withdrawn by virtue of Applicants' amendment and/or the Examiner's reconsideration as noted above.

13. Previous rejection of Claims 29, 30, 57, 62, and 87 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicants' amendment to include a general structural feature in each of the noted claims.

14. Previous rejection of Claim 32 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicants' cancellation of said claim.

***Withdrawn - Claim Rejections - 35 U.S.C. § 101***

15. Previous rejection of Claims 29-32 and 58-59 under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter is withdrawn by virtue of Applicants' cancellation and/or amendment of said claims to include the word "isolated".

***Withdrawn - Claim Rejections - 35 U.S.C. § 102***

16. Previous rejection of Claim 9 under 35 U.S.C. § 102(b) as being anticipated by Kleber-Janke *et al.* is withdrawn by virtue of Applicant's removal of the optional limitation to mole

Art Unit: 1652

percent of lysine. This limitation is in a new claim, Claim 98, whose rejection is addressed below.

17. Previous rejection of Claims 19, 21, and 28 under 35 U.S.C. § 102(b) as being anticipated by Cordero *et al.* is withdrawn by virtue of Applicants' amendment to Claims 19, 21, and 28.

18. Previous rejection of Claim 59 under 35 U.S.C. § 102(b) as being anticipated by Williamson *et al.* is withdrawn by virtue of Applicants' amendment.

## **NEW OBJECTIONS/REJECTIONS**

### ***Objections to the Specification***

19. The specification is objected to for being confusing on page 8. As amended on January 31, 2001, the paragraph discussed "organisms" that are modified. However, the list that follows refers to SEQ ID NOs of sequences that are modified. Appropriate clarification is required.

20. The specification is objected to for being confusing with respect to the sequence listing. The sequence listing contains 74 sequences. Every SEQ ID NO is mentioned in the specification and/or the claims except SEQ ID NOs: 33-34. It is unclear why said sequences are in the sequence listing if they are not described in the specification. All SEQ ID NOs in the sequence listing must be described in the specification. Appropriate correction or clarification is required.

***Objections to the Claims***

21. Claims 10, 13, 20, 23, 24, 56, 69, 71, 85, and 86 are objected to for having an improper Markush group. The pairs of substitutions should be joined by an "and" not an "or" as claimed. Appropriate correction is required.
22. Claim 73 objected to under 37 C.F.R. § 1.75 as being a substantial duplicate of Claim 64. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See M.P.E.P. § 706.03(k).
23. The following claims are objected to for depending from objected to claims: 11, 12, 14-18, and 96.

***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

24. Claim 99 is rejected under 35 U.S.C. § 132 and 35 U.S.C. § 112, first paragraph, new matter, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment filed on September 3, 2002 adds new matter to Claim 99 as follows: "at least 15-25 mole % lysine".



Art Unit: 1652

Applicant is required to cancel the new matter in the reply to this Office Action or to identify clear support (including page and line number) for the above phrase in the specification as originally filed.

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

25. Claim 29 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "conservative substitution" is unclear as to its metes and bounds. Applicants amended the specification to include on "conservatively substituted variants" which, they attest, are limited to the substitutions listed on page 10 of the specification. However, this citation in the specification is unclear. For example, in the first group of "conservative substitutions", only an arginine can substitute for a lysine; in the second group of "conservative and essential amino acid substitutions", a threonine can substitute for a lysine. Thus, the definition of "conservative substitution" is unclear. Moreover, the term is also unclear by virtue of the unclear sentence structure. The Examiner suggests substituting it with ---conservatively substituted polypeptide thereof--- provided that the term "conservatively substituted" can be made clear in light of the specification as originally filed.

***Claim Rejections - 35 U.S.C. § 102***

26. Claims 98-99 are rejected under 35 U.S.C. § 102(b) as being anticipated by Kleber-Janke *et al.* (Planta (1997) 203:332-340). The instant claims are drawn to polypeptides having at least 30% sequence identity to SEQ ID NO:2 and having at least 15% mol % lysine composition.

Kleber-Janke *et al.* teach a barley polypeptide having 43% sequence identity with SEQ ID NO:2 and having 10 (out of 68 residues) lysine residues for a mole percent of 14.7%, which can be rounded up to 15% (see previously attached alignment).

The Examiner notes that Applicants have previously argued analogous rejections based on the priority date that should be afforded to the instant subject matter. Applicants have argued that this subject matter deserves priority back to application 08/740,682, filed on November 1, 1996 (which the instant application is a continuation-in-part of). This application is currently unavailable in the publication division awaiting patenting. If Applicants' assessment that 08/740,682 discloses the invention in Claims 98-99 is concurred by the Examiner, the instant rejection will be withdrawn.

***Summary of Issues Pending***

27. The following is a summary of the issues pending in the instant application.
- a) Compliance with the sequence rules.
  - b) The specification stands objected to for being confusing on page 8.
  - c) The specification stands objected to for being confusing with respect to the sequence listing. .

- d) Claims 10, 13, 20, 23, 24, 56, 69, 71, 85, and 86 stand objected to for having an improper Markush group.
- e) Claim 73 stands objected to under 37 C.F.R. § 1.75 as being a substantial duplicate of Claim 64.
- f) The following claims stand objected to for depending from objected to claims: 11, 12, 14-18, and 96.
- g) Claim 99 stands rejected under 35 U.S.C. § 132 and 35 U.S.C. § 112, first paragraph, new matter.
- h) Claim 29 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to the term "conservative substitution"
- i) Claims 98-99 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Kleber-Janke *et al.*

### ***Conclusion***

28. Claims 10-18, 20, 23, 24, 56, 69, 71, 73, 85, and 86 are objected to. Claims 29 and 98-99 are rejected. Claims 9, 19, 21, 22, 25, 28, 30, 31, 54, 55, 57-59, 61, 63-67, 70, 72, 76-84, 87, 96, and 97 are allowed in the Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution. The instant Office action is **NON-FINAL**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

Art Unit: 1652

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK  
November 6, 2002

11/6/02